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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/857,554	07/23/2001	Edmund Scholl	24669	6387

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NATH & ASSOCIATES  
1030 15th STREET  
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WASHINGTON, DC 20005

EXAMINER

HOWARD, SHARON LEE

ART UNIT	PAPER NUMBER
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1615

DATE MAILED: 04/05/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	09/857,554	SCHOLL, EDMUND	
	<b>Examiner</b>	<b>Art Unit</b>	
	Sharon L. Howard	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 09 January 2004.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 22-55 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 22-55 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
     Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
     Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. §§ 119 and 120

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
     a) ☐ All    b) ☐ Some \*    c) ☐ None of:  
         1. ☐ Certified copies of the priority documents have been received.  
         2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
         3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
     \* See the attached detailed Office action for a list of the certified copies not received.
- 13) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.  
     a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                  | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____  |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)         | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 6) <input type="checkbox"/> Other: _____                                    |

The examiner acknowledges receipt of the response to notice of non-compliant amendment filed on 12/16/03.

The objection to the specification and the 112 (first and second paragraph) rejections for claims 22-55 have been obviated.

Claims 22,30,46 are currently amended.

Claims 22-55 are pending.

#### **DETAILED ACTION**

##### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 22-30 are rejected under 35 U.S.C. 102(b) as being anticipated by Wahlig et al (U.S. Patent No. 4,291,013).

Wahlig teaches a composition consisting of a drug delivery system comprising collagen, which is resorbable in the body. Wahlig teaches collagen in lyophilized form, with a delayed release of active materials. See column 3, lines 11-30 and column 2, lines 36-67. Wahlig teaches collagen having spheroidal shaped bodies of various dimensions, for example, spheroids with a diameter of 0.5-10mm, and granulates with a diameter of 0.1-5 mm. Wahlig also teaches that the composition can also be formed

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into a powder. See column 2, lines 63-68, bridging column 3, lines 1-10. Wahlig teaches the active materials consists of antibiotics such as two or more aminoglycoside antibiotics which include gentamycin and clindamycin. See column 5, lines 8-40. In addition, Wahlig teaches calcium phosphate and tricalcium phosphate. See column 6, lines 1-9. The reference clearly teaches resorbable collagen in lyophilized form with a delayed release of active materials.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 22-28,30-55 are rejected under 35 U.S.C. 102(b) as being anticipated by Chu (U.S. Patent No. 5,219,576).

Chu teaches collagen wound healing matrices and a method for making biodegradable collagen implants, formed of collagen fibrils that are not chemically cross-linked, having a bulk density of 0.01 to 0.3 g/cm<sup>3</sup> and having at least about 80% of pores which normally has a pore size of 35 to 250 microns in diameter. Chu further discloses that the wound healing matrix serves as an effective sustained delivery system for bioactive agent. See abstract and column 6, line 68, bridging column 7, lines 1-10.

Chu discloses a method for making collagen implants by providing an acidic aqueous solution of collagen, precipitating the collagen from the solution, and forming a

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homogeneous dispersion of the precipitated collagen fibrils, casting the dispersion in a mold to a desired thickness, flash-freezing the cast dispersion at a temperature below about -20 degrees C; and lyophilizing the frozen cast dispersion to form a collagen implant. Bioactive additives can be added to the homogeneous dispersion before or after the pH of the solution has been adjusted. See column 2, lines 18-36. Chu teaches that glycosaminoglycans, bioactive and/or non-bioactive agents are added to the collagen dispersion prior to flash-freezing and lyophilization. See column 5, lines 15-18. Adding heparin to the dispersion has been found to affect the pore size of the implant. See column 6, lines 52-58. Chu also teaches that the fibrous implants are about 2 to about 8 mm thick and that the implants may easily be cut to shape in order to fill the wound closely. See column 7, lines 15-30.

The reference meets the claims of the instant application.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 22,31-55 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wallace et al. (U.S. Patent No. 4,789,663) in view of JP 41007119A.

Wallace teaches methods of repairing bone defects or reconstructing a matrix for new bone growth, by implanting in the defect, purified, reconstituted fibrillar collagen (Type I), which may be in lyophilized form. See column 3, lines 54-64, and column 4,

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lines 22-32. Wallace teaches a method for preparing lyophilized collagen gel. See the example at column 10, lines 63-68, column 11, lines 1-16. Wallace also teaches a method for preparing bone collagen powder. See column 11, lines 17-68, column 12, 39.

Wallace does not particularly teach an active ingredient.

However, the Japanese reference teaches a collagen sponge containing silver sulfadiazine. See abstract.

It would have been obvious to one of ordinary skill at the time the invention was made to use the composition taught by Wallace, because Wallace teaches methods of repairing bone defects by implanting purified, reconstituted fibrillar collagen, which may be in lyophilized form. The use of an active ingredient in the composition taught by the Japanese reference would have been obvious to one of ordinary skill of the art because the Japanese reference teaches a composition which is useful for the purpose of incorporating silver sulfadiazine in a collagen sponge matrix.

The expected result would be a collagen sponge matrix which may be in lyophilized form, containing an active ingredient which is poorly soluble in water.

No claims are allowed.

### ***Conclusion***

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

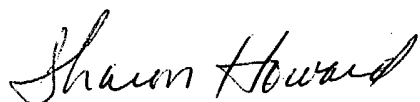
U.S. Patent No. 3,471,598 (Battista) teaches a method of producing sponges.

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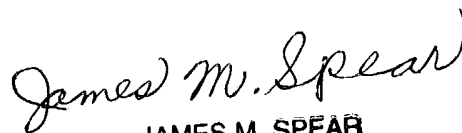
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sharon L. Howard whose telephone number is (571) 272-0596. The examiner can normally be reached on 9:00am - 5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K. Page can be reached on (571) 272-0602. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Sharon Howard  
March 31, 2004



JAMES M. SPEAR  
PRIMARY EXAMINER

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